

RECEIVED
CENTRAL FAX CENTER

JUN 01 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/803,126
Applicant(s) : James Robert Schwartz et al.
Filed : 3/17/2004
Title : AUGMENTATION OF PYRITHIONE ACTIVITY OR
A POLYVALENT METAL SALT OF PYRITHIONE
ACTIVITY BY ZINC-CONTAINING LAYERED
MATERIAL
TC/A.U. : 1616
Examiner : Ernest V. Arnold
Conf. No. : 4865
Docket No. : 9183M&
Customer No. : 27752

DECLARATION OF JAMES R. SCHWARTZ UNDER 37 CFR 1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22312-1450

Dear Sirs:

I, James Robert Schwartz, hereby declare and say the following:

1. I have been a full-time employee of The Procter & Gamble Company for 19 years and my current position with the company is Research Fellow, P&G Beauty. I hold a B.A. in Chemistry from Kenyon College, 1982 and a PhD in Chemistry from the University of Illinois, 1986.
2. I am one of the named inventors on the above-entitled application and am familiar with the December 1, 2005 Office Action in that application.
3. The claimed invention in the above-entitled application:
A composition comprising:
a) an effective amount of pyrithione or a polyvalent metal salt of a pyrithione;

Appl. No. 10/803,126
 Atty. Docket No. 9183M&
 Customer No. 27752

- b) an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1.
4. The Office Action of December 1, 2005 contains an assertion that Gavin et al. (WO 01/00151) discloses a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt, such as zinc carbonate, and an anionic deterative surfactant for a topical carrier thus reading on instant claims 1-3 and 15-17. The Office Action asserts that it interprets zinc carbonate to be synonymous with basic zinc carbonate as defined in the instant specification. The Office Action asserts that the zinc-containing layered material (zinc carbonate) is present from 0.001% to 10% by weight of the composition preferably 0.1% to 2% by weight and in a ratio of to the antimicrobial active agent (zinc pyrithione) from about 5:100 to about 5:1. The Office Action asserts that since the composition is the same and in the same proportions as the instantly claimed invention, then the composition of Gavin et al. would inherently have an augmentation factor of greater than 1. The Office Action further asserts that the Patent & Trademark Office is not equipped with the scientific equipment to compare the composition of Gavin et al. to the instantly claimed invention but when the compositions are comprised of the exact same materials and would inherently have the exact same properties then the burden is appropriately shifted to the Applicant to demonstrate unexpected results otherwise.
5. However, "zinc carbonate" is not synonymous with "basic zinc carbonate" as asserted above. Table 1 below contains a summary of the differences between the two materials: "zinc carbonate" and "basic zinc carbonate."

Table 1¹ is a brief tabular summary comparing some of the physical properties difference between the two materials as shown below:

TABLE 1		
	Basic Zinc Carbonate	Zinc Carbonate
Chemical Formula	$\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2$	ZnCO_3
Molecular Weight	549.01	125.4
Percent Zinc	59.55	52.15
Percent Carbon	4.38	9.58
Percent Hydrogen	1.10	0
Crystal System	Monoclinic-Prismatic H-M Symbol: (2/m) Space Group: C 2/m	Trigonal-Hexagonal Scalenohehdral H-M Symbol: $\bar{3} 2/m$ Space Group: $R\bar{3}c$

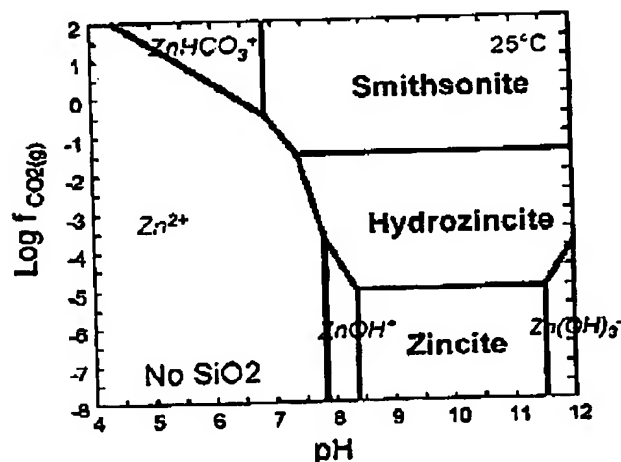
Appl. No. 10/803,126
 Atty. Docket No. 9183M&
 Customer No. 27752

Name of Naturally Occurring Mineral	Hydrozincite	Smithsonite
CAS#, synthetic version	5263-02-5	3486-35-9
CAS#, natural version	12122-17-7	14478-25-6

1. Gaines, RC, Skinner, HCW et al. "Dana's New Mineralogy: The System of Mineralogy of James Dwight Dana and Edward Salisbury Dana" Wiley-Interscience, 1997.

Table 1 demonstrates that basic zinc carbonate and zinc carbonate are both well-defined chemical entities with quite different properties, as reflected in the assignment of different CAS numbers as well as very different properties and nomenclature for the corresponding naturally occurring materials. Therefore, Table 1 demonstrates that zinc carbonate and basic zinc carbonate are two very different materials.

6. The phase diagram² provided below for zinc materials also clearly differentiates basic zinc carbonate (Hydrozincite) and zinc carbonate (Smithsonite) as occurring under very different conditions:



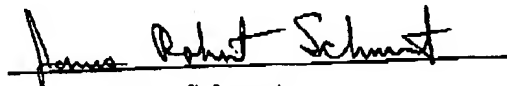
2. McPahil, DC, Summerhayes, E et al. "The Geochemistry and Mobility of Zinc in the Regolith" in "Advances in Regolith: Proceedings of the CRD LEME Regional Regolith Symposium, 2003" IC Roach, Ed., CRC-LEME, 2003, pp 287-291.

The phase diagram identifies the physical conditions (pH and CO2 pressure) under which the various zinc minerals form. Smithsonite (zinc carbonate) only forms at very high carbon dioxide pressures, whereas hydrozincite (basic zinc carbonate) occurs under very different conditions - several orders of magnitude lower carbon dioxide levels.

Appl. No. 10/803,126
Atty. Docket No. 9183M&
Customer No. 27752

Zinc carbonate has a molecular structure that is not considered to be lamellar, or layered, while basic zinc carbonate is a layered structure. These different crystal structures are reflected in Table 1, above, in the different designations of crystal systems for these materials (Gaines, RC, Skinner, HCW et al. "Dana's New Mineralogy: The System of Mineralogy of James Dwight Dana and Edward Salisbury Dana" Wiley-Interscience, 1997). Thus, zinc carbonate is not a "zinc layered material" and is not effective for the present application.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application of any patent issued thereon.



James Robert Schwartz

Dated: 6/1/06

18 U.S.C §1001 Statements or Entries Generally

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry shall be fined no more than \$10,000 or imprisoned not more than five years, or both.